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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,393	08/20/2004	Mitsuaki Kuwano	04561/HG	7247

1933 7590 04/24/2009

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EXAMINER	
BARHAM, BETHANY P	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,393	KUWANO ET AL.	
	Examiner	Art Unit	
	BETHANY BARHAM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of IDS filed on 2/23/09 is acknowledged. Receipt of Applicant's response and claim amendments filed on 2/23/09 is also acknowledged. Claims 8, 10 and 12 are pending and rejected.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/09 has been entered.

MAINTAINED REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Peyman (US 6,395,294).

The instant claims are drawn to a method of treating a disease of a posterior segment of an eye comprising administering subconjunctivally to a patient an effective amount for treatment of an injection comprising fine particles containing a drug and enabling the concentration of the / drug in a retina-choroid to be sustained, wherein the disease of the posterior segment of the eye is uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy or retinal detachment, and a particle diameter of the fine particles is 50 nm to 150 μm.

- Peyman discloses a drug delivery system (subconjunctival injection) to a posterior segment of an eye comprising fine particles containing a drug which are subconjunctivally administered, wherein the posterior segment of the eye is a vitreous body (col. 3, lines 12-27, 36-43; col. 4, lines 23-24, 33- 46). With respect to claim 8, Peyman discloses a method of treating a disease of a posterior segment of an eye (a surgical method to alleviate a structural disorder of the eye caused by the vitreous) comprising subconjunctivally administering to a patient an effective amount of an injection comprising fine particles containing a drug. Peyman discloses the structural disorder of the eye caused by the vitreous is uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion or central retinal artery occlusion (col. 1, lines 14 - col. 2, line 25; col. 3, lines 12-27, 36-43; col. 4, lines 23-24, 33-46, 58-62).

- With respect to claims 10, Peyman discloses the therapeutic agent may be incorporated into a vesicle such as a microsphere made of polyglycolic or polylactic acid (biodegradable polymer) (col. 2, lines 52-54; col. 3, lines 36-42; col. 5, lines 38-44).
- With respect to claim 12, Peyman discloses the drug can be dexamethasone (anti-inflammatory/immunosuppressor), or triamcinolone, or betamethasone (anti-inflammatory/immunosuppressor) (claim 1; col, 4, lines 45-46, 58- 61 ; col. 5, lines 4-19), which are the same drugs disclosed in the instant application. Therefore the drug is considered to be a drug for treatment/prevention of uvetis, cytomegalovirus retinitis, age-related macular degeneration, diabetic retinopathy, proliferative vitreoretinopathy, retinal detachment, pigmentary retinal degeneration, central retinal vein occlusion or central retinal artery occlusion.

Response to Arguments

Applicant argues that the prior art discloses a surgical method for the removal of the vitreous. However, the Examiner respectfully points out that the open "comprising" language of the claims does not exclude additional steps, and as such the prior art Peyman that teaches administering a composition of polymer and drug via injection to the posterior of the eye to treat various diseases anticipates the instant claims. Applicant's also argue that the size disclosed by Peyman "does not disclose or suggest that is it able to enable the drug concentration in a retina-choroid to be sustained by a subconjunctival administration of an injection comprising fine particles". However, the Examiner respectfully points out that Peyman discloses that the particle size must be

less than 50 microns, which is within the range instant claimed and as such anticipates the range.

New Rejections

Claims 8, 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wong et al (US 5,869,079) (as cited by Applicant's IDS).

The instant claims are disclosed above.

- Wong et al teach compositions and methods of biodegradable implants that provide a controlled, sustained drug release (Col. 1, lines 66-68). Their implant formulation can be used for the treatment of ocular conditions and can be implanted at various sites including posterior chamber, vitreous cavity, suprachoroidal space, subconjunctival etc. (Col. 3, line-4, lines Col.6, lines 27-34). Their implants may be administered in a variety of ways including injection (Col.7, lines 15-18). Their implants that are introduced into the suprachoroid deliver drugs to the choroid and to retina (Col.6, lines 38-43). Their teachings include use of these implants for medical and veterinary uses (Col. 1, lines 42-43). The particle size of spheres is taught to include 2 microns to 3 mm (col. 7, lines 50-51) (meeting the limitations of claim 8).
- Their teachings include biodegradable hydrogels (Col.6, lines 10-12). Controlled release of drug can be achieved by slow release of drug from hydrogel. Their controlled drug release formulation contains hydrophobic polymers including ethylcellulose (Col.3, lines 48-49) which forms a drug suspension of hydrophilic drugs (Col.3, lines 41-44) similarly their hydrophobic drugs (Col.2, lines 63-67)

form suspension in hydrophilic polymers like low molecular weight methyl cellulose (Col.3, lines 7-9) (meeting the limitations of claim 10).

- Their drugs include prednisolone, dexamethasone, etc. (Col.3, lines 4-5) (meeting the limitations of claim 12).

Claims 8, 10 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Bowman et al (US 6,378,526) (as cited by Applicant's IDS).

The instant claims are disclosed above.

- Bowman et al teach intrascleral injection of a therapeutic for delivery to the posterior segment of the eye to treat macular degeneration, vein occlusion and diabetic retinopathy (abstract, claim 1 and 20-21). Injections taught by Bowman et al are to be of a particle size of 20-40 microns, but that particles may be larger or smaller depending on the application and that the preferred method includes injection thru a cannula (col. 4, lines 65-col. 5, line 2 and col. 5, lines 65-67) (meeting the limitations of claim 8).
- Bowman et al teach various polymeric suspending agents that are biodegradable and biocompatible for sustained release including dextran, polyethylene glycol, etc (col. 9, lines 25-44) (meeting the limitations of claim 10).
- Bowman et al teach drugs include prednisolone, dexamethasone, etc. (col. 8, lines 36-37) (meeting the limitations of claim 12).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)-272-6175. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bethany Barham
Art Unit 1615

/Tracy Vivlemore/
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